

Remarks/Arguments:

The pending claims are 68, 70-81, 84, 93-112, and 129-133.

Paragraph 3 of the Office Action has rejected claims 68, 71-81, 93-112, and 129-133 under 35 U.S.C. § 112, first paragraph. The Office Action contends that certain recitations in the claims "contain[] subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The rejection is traversed.

**EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." MPEP 2163, Rev.6, Sept. 2007, p. 2100-172. "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163.02, p. 2100-186. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP § 2163.02, p. 2100-186. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-176.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-176. *Accord*, MPEP § 2163 III.A, p. 2100-185. "Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-177. "Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art. . . Information which is well known in the art need not be described in detail in the specification." MPEP 2163 II.A.2, p. 178 (citation omitted).

"Possession may also be shown by a clear depiction of the invention in detailed drawings . . . which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." MPEP § 2163 II.A.3(a), p. 2100-178.

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed." MPEP §2163 III.A., p. 2100-185; § 2163.04 I, p. 2100-187.

THE REJECTION OF CLAIMS 68, 71-81, 93-112, 129-133 UNDER 35 U.S.C. § 112

Claim 68

Claim 68 recites, in part, a "first distal portion has a downstream end forming a skirt."

The Office Action contends that the skirt, recited in claim 68, "is not recited or described in the specification." One skilled in the art would recognize that at least the embodiment illustrated in Fig. 6 shows a skirt in the form of frustoconical part 78. The Office Action has not explained why a person skilled in the art would not recognize that Fig. 6 shows this feature. Since the subject matter of a claim need not be described *in haec verba*, consideration of the specification and figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention recited in claim 68. § 2163, p. 2100-176.

Claims 71 and 109

Claim 71 recites "said primary graft body is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires." Claim 109 recites "at least one of the first graft body and the second graft body is circumferentially reinforced by a metal wire structure."

Page 2 of the Office Action contends that "circumferentially reinforced at locations along its length" and "circumferentially reinforced" are not described. Applicants disagree. Based upon the embodiments illustrated at least in Figs. 1A, 1B, and 6, one skilled in the art would recognize that graft bodies 72, 76, 78, 80, and 86 are circumferentially reinforced by a metal

wire structure and circumferentially reinforced at locations along their length by a plurality of separate spaced apart wires. Referring to Fig. 1A, for example, parts 12, 14, 16, and 18 are constructed as four separate parts. (page 22, lines 17-22).

Claim 73

Claim 73 recites that "at least one of the reinforcement wires is attached to said primary graft body via sutures." Page 2 of the Office Action contends that

"sutures" are not mentioned as being used to attach "reinforcement wires" -- also not specifically described in the specification -- to a graft body (i.e., wires functioning as "reinforcement" are not described).

Applicants disagree.

Based upon the embodiments illustrated at least in Figs. 1A, 1B, and 6, one skilled in the art would recognize that graft bodies 72, 76, 78, 80, and 86 are reinforced by wires. For example, the specification explains that the stents "may carry a tubular graft layer" that "may be disposed externally of the stent." (page 12, lines 3-9; see also, page 32, lines 4-5). One skilled in the art would also recognize that sutures may be used. See, e.g., page 10, lines 20-27; page 12, lines 11-13.

Claim 81

Claim 81 recites that

one of the reinforcement wires is located at one end of the primary graft body and has alternate crests or apices extending beyond said one end of the primary graft body.

The embodiment shown in Fig. 6, for example, illustrates crests at end 82 that extend beyond an end of the graft. See, e.g., page 31, line 26-page 32, line 4. One skilled in the art would recognize that the embodiment illustrated in Fig. 6 provides support for the recitations in claim 81.

Claims 93, 107-109

These claims recite "inlet" ends and "outlet" ends. Pages 2-3 of the Office Action contend that the specification does not describe these terms. As indicated above, however, "[t]he subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP § 2163.02, p. 2100-186. One of skill in the art would recognize that the graft bodies recited in these claims must have an inlet end and an outlet end because, for example

[a] stent is used to provide a prosthetic intraluminal wall e.g. in the case of a stenosis to provide an unobstructed conduit for blood in the area of the stenosis. (page 2, lines 7-10).

Claim 111

Claim 111 recites "at least one wireform has a closed sinusoidal shape." Page 3 of the Office Action contends that "the specification does not describe a graft with a 'closed sinusoidal shape.'" Applicants disagree. The specification discloses that embodiments of the hoops are formed in a sinuous configuration. See, for example, Abstract at line 9; page 8, lines 8-10 ("Each of the first and second stents may comprise a sinuous wire formed into a tubular configuration."); page 23, lines 18-20 ("[I]n each hoop 20 the nitinol wire follows a sinuous path to define a plurality of circumferentially spaced apices 22.") Accordingly, one skilled in the art would recognize that "closed sinusoidal shape" is supported by the specification.

Claims 105, 106

Claim 105 recites that "one of the first graft body and the second graft body comprises a skirt portion." Claim 106 recites that the "skirt portion is about 18 mm in length." Page 3 of the Office Action contends that these features are not described in the specification. Applicants incorporate by reference their discussion above regarding a skirt in claim 68. Frustoconical part 78 corresponds to either frustoconical part 14 or 18, each of which is about 18 mm. (page 26, lines 5-6).

Claims 129, 130

Page 3 of the Office Action contends that "the specification does not describe first and second graft bodies and a metal wire structure having differing radiopacity or 'radiographic indicia' or a 'composite radiographic image' for indicating the 'rotational orientation' of at least one of the first and second graft bodies and a metal wire structure in a body lumen." Applicants disagree.

The specification states, in part:

Using a radiopaque marker 120 disposed on proximal end of the prosthesis, the introducer is rotated until proper alignment of the prosthesis is obtained. In the illustrated embodiment, radiopaque marker 120 is a platinum wire twisted around an apex of the prosthesis in a "V" shape. To ensure proper alignment, the stent should be rotated until only the profile of the V is seen and shows up as a straight line rather than a "V". (page 39, lines 15-23).

One of skill in the art would recognize that Applicants' specification supports claims 129 and 130.

For all of the above claims, the Office Action has not "[e]stablish[ed] a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed" as required by the MPEP § 2163 III.A, p.2100-185.

Since claims 72, 76, 97, 103 and 133 have only been rejected based upon § 112, and since the application supports the recitations in each of these claims, Applicants request the PTO to withdraw the § 112 rejections and to again indicate that those claims are allowable.

THE REJECTION OF CLAIMS 68, 70, 84, 93-96, 98-102,
104, 105, 107-110, 112 AND 129-132 UNDER 35 U.S.C. § 102

Claims 68, 70, 84, 93-96, 98-102, 104, 105, 107-110, 112, and 129-132 have been rejected under 35 U.S.C. § 102(e) as anticipated by Barone et al. (U.S. Patent No. 5,360,443). The rejection is traversed. These rejections are substantially the same as the rejections in the October 23, 2007 Office Action. Accordingly, and in addition to the remarks that follow, Applicants incorporate by reference the response they filed on April 21, 2008 following the October 23, 2007 rejections.

Claim 68

Claim 68 recites, in part, "a second graft. . .adapted to be intravascularly inserted into a lumen of said first graft." Paragraph 8, page 6 of the Office Action contends that securing means 192 of Barone is

"adapted to be intravascularly inserted into a lumen of the first graft 160." That is, element 192 is shown to be already inserted into element 160, while both elements are within a blood vessel.

Applicants respectfully submit that the Office Action incorrectly interpreted "adapted to be intravascularly inserted." One skilled in the art would understand that embodiments of Applicants' claimed invention are adapted to insert a second graft into a lumen of a first graft after the first graft has been first inserted into the patient's vessel - rather than inserting the second graft into a lumen of the first graft while the two grafts are outside the patient's body. This claim aspect is described at least in the following embodiments:

- A female stent is delivered at the site of use and allowed to expand. "The first [male] stent may then be delivered percutaneously or by a "cut down" technique to a site distal of the second [female] stent such that the male engaging portion . . . is entered into the expanded female cooperating portion." (page 6, lines 7-18) (emphasis added)

- "In some embodiments the second distal stent portion may comprise a female cooperating portion which is adapted to engage a male engaging portion of a[sic] another stent adapted to extend in the other branched blood vessel such that, in use, the bifurcated stent can be connected in situ to the other stent." (page 7, lines 18-23) (emphasis added)
- "the bifurcated prosthesis can be connected to another prosthesis which extends into the other branched artery. The prosthesis can be delivered percutaneously or by "cut down" methods and connected together in situ." (page 15, lines 11-15) (emphasis added)
- "In service, the male engaging portion 88 of the other prosthesis 86 is entered into and engaged with the female cooperating portion 78 of the bifurcated prosthesis 70 in situ in the manner herein before described." (page 32, lines 17-21) (emphasis added)

The Office Action appears to contend that the phrase "adapted to be intravascularly inserted" is disclosed in Barone because element 192 is coupled to element 160 and that both elements are inserted into a vessel - regardless of the fact that they are coupled together prior to insertion into the vessel. See Figs. 7, 8 and col. 8, lines 23-53; col. 9, lines 13-18 of Barone. Figs. 9-12 of Barone illustrate a method for repairing an abdominal aortic aneurysm and iliac aneurysm with the aortic graft illustrated in Fig. 6. One skilled in the art would understand that the devices shown in Figs. 7 and 8 are inserted as a single unit, and that the securing devices 192 are not intravascularly inserted into tubular passageways 191.

In addition, pages 6-7 of the Office Action have not given any patentable weight to the recitation that a second graft is "adapted to" be intravascularly inserted, stating that such a claim element "is not necessarily a positive limitation, but only requires the ability to so perform." The Office Action's contention directly contradicts MPEP § 2173.05(g) and the case cited therein: *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976). The MPEP states:

limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly.

The MPEP quotation supports Applicants' contention that the phrase "adapted to be intravascularly inserted" must be given patentable weight as a positive limitation and cannot be disregarded.

For at least all of the above reasons and the reasons incorporated by reference from Applicants' April 21, 2008 response, claim 68 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Barone.

Claims 129, 130

These claims recite, in part, a "different radiopacity."

Despite Applicants' arguments in their April 21, 2008 response, page 7 of the Office Action states:

The Examiner indeed considered the functional limitations of claims 129 and 130 and determined that since the graft bodies and the wire structure inherently possess different radiopacity or radiographic indicia, the functions of aligning or orienting the bodies and structure would naturally and inherently follow (i.e., the main purpose of radiographic imaging of a surgical device is for the viewing and positioning of the device within a patient's body).

Applicants respectfully submit that an Examiner's attempt to determine inherent characteristics of a device shown in a reference may not be relied upon to reject a claim under §102. Instead, the MPEP requires an Examiner to rely on extrinsic evidence:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled in with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. MPEP § 2131.01 III, p.2100-68 (emphasis added).

The Office Action has not provided any evidence making clear that Barone inherently shows the features recited in these claims.

Accordingly, for at least the reasons set forth in the April 21, 2008 response and for the additional reasons set forth herein, these claims are not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Barone.

Claim 131

Claim 131 recites two introducers for performing specifically recited functions. Applicants' April 21, 2008 response specifically pointed out why Barone does not disclose the features recited in claim 131. The current Office Action, however, states only that Barone discloses introducers 201. The Office Action has not, however, addressed the remainder of Applicants' contentions. Accordingly, for at least the reasons set forth in the April 21, 2008 response and these additional reasons, claim 131 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Barone.

Claim 132

Claim 132 depends from claim 109, which recites, in part
said inlet end of said second graft body being attachable in an overlapping
relationship with said outlet end of said first graft body while inside a vessel.

Claim 109 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Barone for the reasons set forth in Applicants' April 21, 2008 response. Since claim 132 depends from claim 109, claim 132 is also not subject to the rejection for at least the same reasons. The Office Action's contentions do not address Applicants' arguments regarding claim 109. Accordingly, for at least the reasons set forth in the April 21, 2008 response and for the additional reasons stated herein, claim 132 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Barone.

THE REJECTION OF CLAIMS 71, 73-75,
77-81, AND 111 UNDER 35 U.S.C. § 103(a)

These rejections are substantially the same as the rejections stated in the October 23, 2007 Office Action. Accordingly, Applicants incorporate by reference their April 21, 2008 response. Since the Office Action's "Response to Amendment" does not provide any new reasons for these rejections, Applicants rely upon their previously presented arguments.

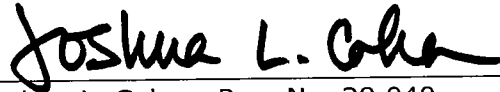
Appln. No.: 10/692,886
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Reply to Office Action of July 31, 2008

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CONCLUSION

For all of the above reasons, claims 68, 70-81, 84, 93-112, and 129-133 are in condition for allowance and an early indication of allowance is respectfully requested.

Respectfully submitted,



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